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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,349	06/20/2001	Yasir Skeiky	014058-009070US	4456

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/886,349	Applicant(s) SKEIKY ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22April2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) 20-69 and 76-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 70-75 and 83-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-88 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/4/02</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants' Response to Restriction, received 22 April 2004, is acknowledged. Applicants elect, with traverse, Invention I, claims 1-19, 70-75, 83-88, drawn to polypeptides, classified in class 424, subclass 248.1.

Applicant's traversal is on the grounds that all four inventions stem from a common concept and theory and therefore prosecution of all four inventions would not place a substantially greater burden on the examiner. This is not found persuasive because of the reasons put forth in the original restriction and because the inventions have acquired a separate status in the art as shown by their different classification, and because while the searches may overlap, the searches are not coextensive, restriction for examination purposes as indicated is proper. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-88 are pending. Claims 20-69 and 76-82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

3. Claims 1-19, 70-75, and 83-88 are under consideration.

Specification

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-5 and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,627,198. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 5 is drawn to a composition listing one component, a fusion polypeptide comprising (SEQ ID NO:12 or 14) and (SEQ ID NO:2 or 4), wherein the fusion polypeptide has the amino acid sequence of MTB59F (SEQ ID NO:20). Claim 1 of U.S. Pat. No. 6,627,198 is drawn to one component, a purified polypeptide comprising the amino acid sequence of SEQ ID NO:26. SEQ ID NO:20 and NO:26 are identical. Therefore, due to the open language of claims 1-5, i.e., the polypeptide "comprises" designated amino acid sequences, the claims read on claim 1 of U.S. Pat. No. 6,627,198.

7. Claims 1-5 and 19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/359,460. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 5 is drawn to a composition listing one component, a fusion polypeptide, wherein the fusion polypeptide has the amino acid sequence of MTB59F (SEQ ID NO:20). Claim 1 of copending Application No. 10/359,460 is drawn to one component, a purified polypeptide comprising the amino acid sequence of SEQ ID NO:26. SEQ ID NO:20 and NO:26 are identical. Therefore, due to the open language of claims 1-5, i.e., the polypeptide "comprises" designated amino acid sequences, the claims read on claim 1 of copending Application No. 10/359,460

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-4, 6, 8, 17, and 19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 62-64 of copending Application No. 09/597,796. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim 6 is drawn to a composition listing one component, a fusion polypeptide, wherein the fusion polypeptide has the amino acid sequence of MTB72F (SEQ ID NO:16). Claim 62 of copending Application No. 09/597,796 is drawn to one component, a fusion polypeptide comprising the amino acid sequence of MTB72F (SEQ ID NO:16). Both sequences SEQ ID NO:16 are identical. Instant claims 8 and 17 are drawn to a composition comprising a fusion polypeptide comprising the amino acid sequence of MTB72F (SEQ ID NO:16) and BCG as are claims 63 and 64 of copending Application No. 09/597,796. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 70-75 and 83-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite polypeptides which have substitutions in "the active site triad". It is unclear what is meant by this terminology. In addition, is there only one, i.e., "the", active site triad in each polypeptide.

12. Claims 7 and 88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims appear to be identical. Claim 7 is drawn to a fusion polypeptide having the amino acid sequence of SEQ ID NO:18. Claim 88 is drawn to a fusion polypeptide comprising an amino acid sequence of SEQ ID NO:18. Clarification is needed concerning the any differences between the claims.

13. Claims 9-16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims depend from rejected claims.

Conclusion

14. No claims are allowed.

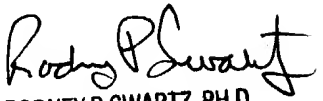
15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

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The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

July 21, 2004